

**HPTN 078 - Enhancing Recruitment, Linkage to Care and Treatment for HIV-Infected Men Who Have Sex with Men (MSM) in the United States  
Report - April 29, 2019**

**Visit Cutoff Date: April 28, 2019  
Table C - Screening Summary by Site**

	<b>Overall</b>	<b>Alabama CRS</b>	<b>Fenway Health CRS</b>	<b>JHU CRS</b>	<b>Ponce de Leon CRS</b>
Total visits at Screening Visit	1305	466	288	281	270
Recruited via DC-RDS					
No	534/1305 (40.9%)	247/466 (53.0%)	73/288 (25.3%)	86/281 (30.6%)	128/270 (47.4%)
Yes	771/1305 (59.1%)	219/466 (47.0%)	215/288 (74.7%)	195/281 (69.4%)	142/270 (52.6%)
Total visits at Screening Outcomes	1305	466	288	281	270
HIV positive	902	290	172	197	243
Unknown	38/902 (4.2%)	20/290 (6.9%)	8/172 (4.7%)	3/197 (1.5%)	7/243 (2.9%)
Virally unsuppressed	154/902 (17.1%)	40/290 (13.8%)	27/172 (15.7%)	37/197 (18.8%)	50/243 (20.6%)
Virally suppressed	710/902 (78.7%)	230/290 (79.3%)	137/172 (79.7%)	157/197 (79.7%)	186/243 (76.5%)
Total Coupons Accepted for Distribution	2871	630	711	828	702
Number Eligible for Enrollment	145	34	27	35	49
Number Enrolled	144	34	27	35	48
Site Activation Date		10-MAY-2016	17-MAR-2016	8-APR-2016	13-MAY-2016
Seed Release Date		06-JUN-2016	29-MAR-2016	13-MAY-2016	24-MAY-2016
		08-JUN-2016	14-APR-2016	19-MAY-2016	27-JUN-2016
		08-AUG-2016	06-MAY-2016	07-JUN-2016	05-AUG-2016
		19-AUG-2016	10-MAY-2016	20-JUN-2016	24-AUG-2016
		22-AUG-2016	31-MAY-2016	27-SEP-2016	31-AUG-2016
		29-AUG-2016	02-JUN-2016	29-SEP-2016	13-OCT-2016
		31-AUG-2016	08-JUN-2016	13-OCT-2016	14-OCT-2016
		29-SEP-2016	13-JUN-2016	18-OCT-2016	28-OCT-2016
		05-OCT-2016	21-SEP-2016	02-NOV-2016	28-OCT-2016
		28-OCT-2016	11-OCT-2016	07-NOV-2016	03-NOV-2016
		13-DEC-2016	01-DEC-2016	05-DEC-2016	09-NOV-2016
		15-DEC-2016	10-JAN-2017	07-DEC-2016	10-NOV-2016
		19-DEC-2016	19-JAN-2017	12-DEC-2016	11-NOV-2016
		07-FEB-2017	19-JAN-2017	13-DEC-2016	16-NOV-2016
		07-FEB-2017	30-JAN-2017	13-DEC-2016	16-NOV-2016
		22-JUN-2017	21-FEB-2017	13-DEC-2016	18-NOV-2016
		19-JUL-2017	23-FEB-2017	16-DEC-2016	01-DEC-2016
			27-FEB-2017	19-DEC-2016	05-DEC-2016
			16-MAR-2017	20-DEC-2016	07-DEC-2016
			17-MAR-2017	27-DEC-2016	08-DEC-2016
			22-MAR-2017	09-JAN-2017	08-DEC-2016

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		29-MAR-2017	10-JAN-2017	08-DEC-2016
		30-MAR-2017	19-JAN-2017	09-DEC-2016
		24-APR-2017	24-JAN-2017	12-DEC-2016
		23-MAY-2017	25-JAN-2017	13-DEC-2016
		20-JUN-2017	26-JAN-2017	13-DEC-2016
		22-JUN-2017	26-JAN-2017	13-DEC-2016
		18-JUL-2017	27-JAN-2017	14-DEC-2016
		07-AUG-2017	02-FEB-2017	15-DEC-2016
		29-AUG-2017	09-FEB-2017	15-DEC-2016
		30-AUG-2017	14-FEB-2017	28-DEC-2016
		11-SEP-2017	23-FEB-2017	04-JAN-2017
		12-SEP-2017	23-FEB-2017	04-JAN-2017
		20-SEP-2017	24-FEB-2017	05-JAN-2017
		20-SEP-2017	27-FEB-2017	12-JAN-2017
		16-OCT-2017	28-FEB-2017	02-FEB-2017
		17-OCT-2017	28-FEB-2017	07-FEB-2017
		17-OCT-2017	01-MAR-2017	07-FEB-2017
		17-OCT-2017	01-MAR-2017	08-FEB-2017
		24-OCT-2017	02-MAR-2017	10-FEB-2017
		25-OCT-2017	02-MAR-2017	15-FEB-2017
		30-OCT-2017	06-MAR-2017	27-FEB-2017
		30-OCT-2017	07-MAR-2017	01-MAR-2017
		30-OCT-2017	07-MAR-2017	01-MAR-2017
		31-OCT-2017	08-MAR-2017	08-MAR-2017
		20-NOV-2017	10-MAR-2017	09-MAR-2017
		29-NOV-2017	13-MAR-2017	09-MAR-2017
			16-MAR-2017	10-MAR-2017
			21-MAR-2017	10-MAR-2017
			22-MAR-2017	15-MAR-2017
			03-APR-2017	16-MAR-2017
			18-APR-2017	22-MAR-2017
			20-APR-2017	17-APR-2017
			20-APR-2017	26-APR-2017
			21-APR-2017	03-MAY-2017
			28-APR-2017	08-MAY-2017
			08-MAY-2017	09-MAY-2017
			15-MAY-2017	15-MAY-2017

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**Table C - Screening Summary by Site**

Overall	Alabama CRS	Fenway Health CRS	JHU CRS	Ponce de Leon CRS
			25-MAY-2017	17-MAY-2017
			05-JUN-2017	17-MAY-2017
			07-JUN-2017	31-MAY-2017
			12-JUN-2017	01-JUN-2017
			15-JUN-2017	02-JUN-2017
			16-JUN-2017	05-JUN-2017
			19-JUN-2017	05-JUN-2017
			19-JUN-2017	08-JUN-2017
			22-JUN-2017	21-JUN-2017
			28-JUN-2017	22-JUN-2017
			12-JUL-2017	05-JUL-2017
			27-JUL-2017	05-JUL-2017
			02-AUG-2017	06-JUL-2017
			14-AUG-2017	11-JUL-2017
			23-AUG-2017	13-JUL-2017
			25-AUG-2017	17-JUL-2017
			28-AUG-2017	17-JUL-2017
			29-AUG-2017	24-JUL-2017
			31-AUG-2017	24-JUL-2017
			18-SEP-2017	24-JUL-2017
			19-SEP-2017	24-JUL-2017
			20-SEP-2017	26-JUL-2017
			21-SEP-2017	08-AUG-2017
			22-SEP-2017	09-AUG-2017
			28-SEP-2017	17-AUG-2017
			10-OCT-2017	22-AUG-2017
			20-OCT-2017	23-AUG-2017
			23-OCT-2017	28-AUG-2017
			24-OCT-2017	13-SEP-2017
			31-OCT-2017	14-SEP-2017
			02-NOV-2017	15-SEP-2017
			09-NOV-2017	18-SEP-2017
			10-NOV-2017	20-SEP-2017
			14-NOV-2017	27-SEP-2017
			15-NOV-2017	27-SEP-2017
			27-NOV-2017	28-SEP-2017
			29-NOV-2017	02-OCT-2017

If a participant is rescreened and assigned a new PTID, then the corresponding old PTID is not included here.

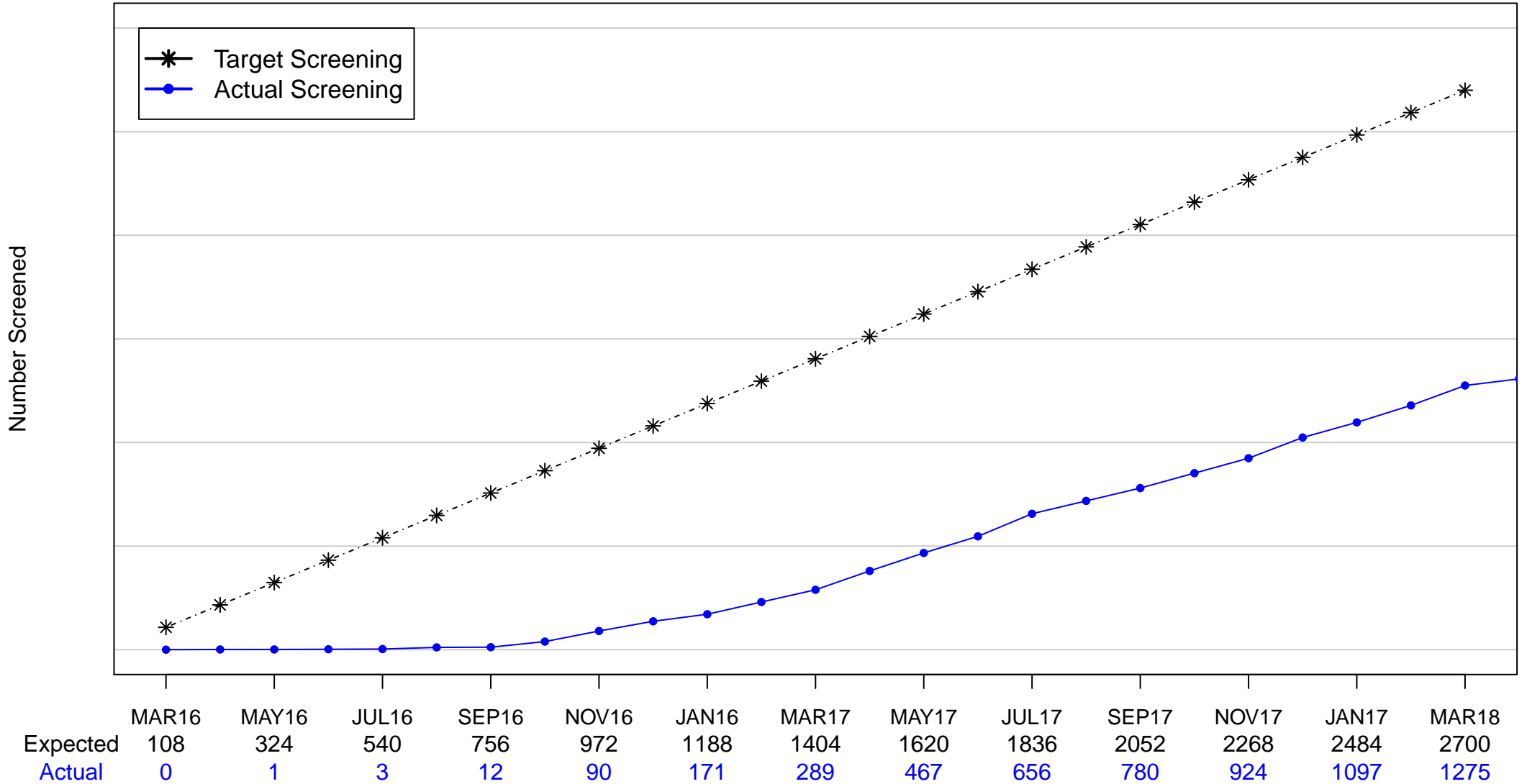
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**Table C - Screening Summary by Site**

Overall	Alabama CRS	Fenway Health CRS	JHU CRS	Ponce de Leon CRS
				04-OCT-2017
				19-OCT-2017
				24-OCT-2017
				26-OCT-2017
				27-OCT-2017
				30-OCT-2017
				30-OCT-2017
				02-NOV-2017
				03-NOV-2017
				06-NOV-2017
				09-NOV-2017
				21-NOV-2017
				21-NOV-2017

If a participant is rescreened and assigned a new PTID, then the corresponding old PTID is not included here.

Figure 1 A. Cumulative Screening – All Sites

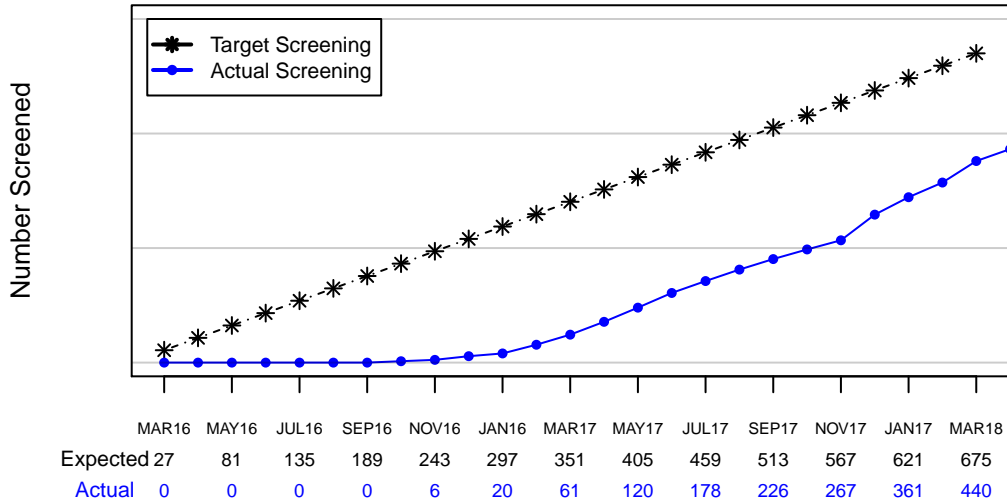
Total Screening: 1307 Screening Target: 2700 Screening Needed: 1393



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 Cumulative Screening  
 Data as of 29Apr2019

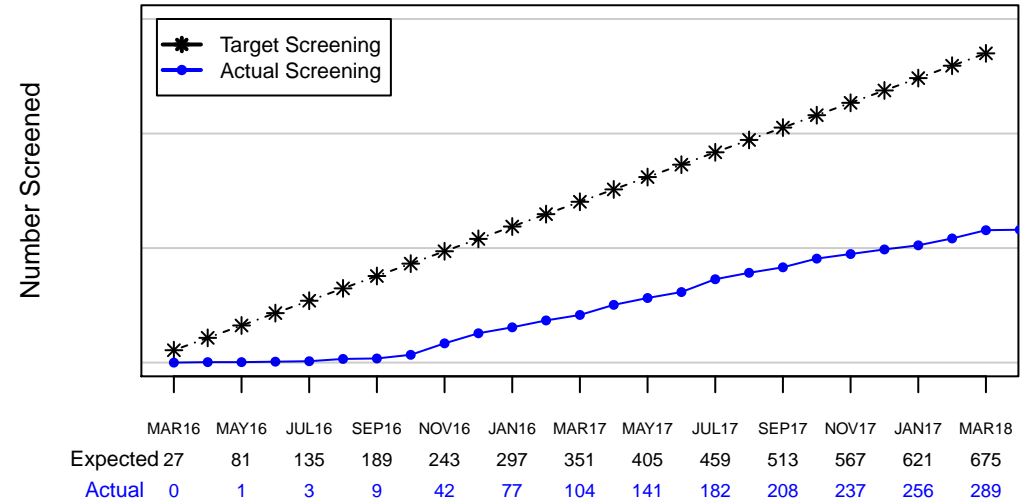
**Figure 1 B. Alabama CRS**

**Total Screening: 466 Screening Target: 675 Screening Needed: 209**



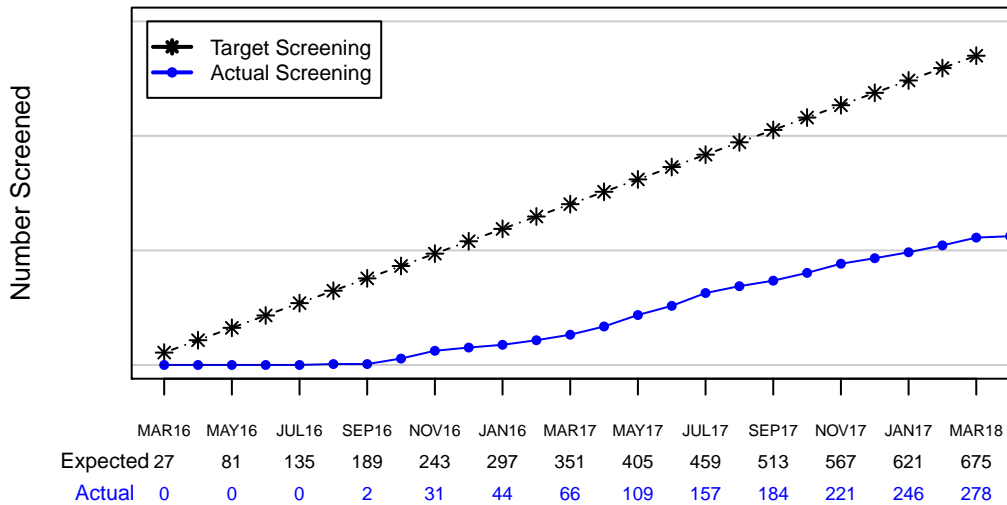
**Figure 1 C. Fenway Health CRS**

**Total Screening: 290 Screening Target: 675 Screening Needed: 385**



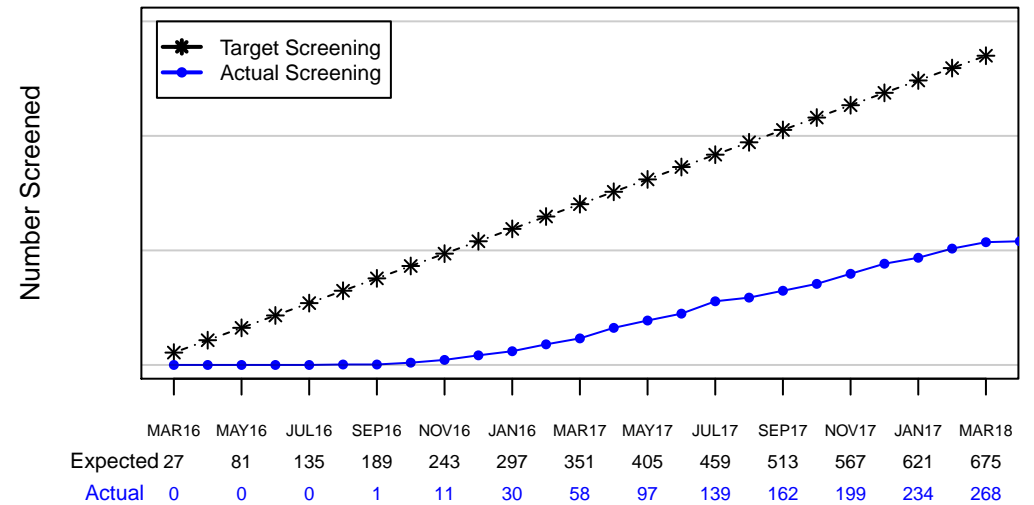
**Figure 1 D. JHU CRS**

**Total Screening: 281 Screening Target: 675 Screening Needed: 394**



**Figure 1 E. Ponce de Leon CRS**

**Total Screening: 270 Screening Target: 675 Screening Needed: 405**



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	Overall	Alabama CRS	Fenway Health CRS	JHU CRS	Ponce de Leon CRS
<b>Screened at Screening Outcomes Visit<sup>1</sup></b>	<b>1305</b>	<b>466</b>	<b>288</b>	<b>281</b>	<b>270</b>
<b>Eligible for Enrollment</b>					
Yes	145/1305 (11.1%)	34/466 (7.3%)	27/288 (9.4%)	35/281 (12.5%)	49/270 (18.1%)
No	1160/1305 (88.9%)	432/466 (92.7%)	261/288 (90.6%)	246/281 (87.5%)	221/270 (81.9%)
<b>Reason Not Enrolled<sup>2</sup></b>					
Did not meet screening criteria	3/1090 (0.3%)	3/398 (0.8%)	0/234 (0.0%)	0/243 (0.0%)	0/215 (0.0%)
Non-reactive/negative HIV	356/1090 (32.7%)	154/398 (38.7%)	95/234 (40.6%)	82/243 (33.7%)	25/215 (11.6%)
Currently virally suppressed	715/1090 (65.6%)	231/398 (58.0%)	137/234 (58.5%)	158/243 (65.0%)	189/215 (87.9%)
Unable to receive care at one of the pre-determined clinics	0/1090 (0.0%)	0/398 (0.0%)	0/234 (0.0%)	0/243 (0.0%)	0/215 (0.0%)
Plan of relocation within 24 months following enrollment	1/1090 (0.1%)	0/398 (0.0%)	1/234 (0.4%)	0/243 (0.0%)	0/215 (0.0%)
Unable or unwilling to provide consent/assent	1/1090 (0.1%)	0/398 (0.0%)	0/234 (0.0%)	1/243 (0.4%)	0/215 (0.0%)
Transgender	1/1090 (0.1%)	0/398 (0.0%)	1/234 (0.4%)	0/243 (0.0%)	0/215 (0.0%)
Active or previous participation in an HIV vaccine trial	0/1090 (0.0%)	0/398 (0.0%)	0/234 (0.0%)	0/243 (0.0%)	0/215 (0.0%)
Current participation in a linkage or ART adherence study	0/1090 (0.0%)	0/398 (0.0%)	0/234 (0.0%)	0/243 (0.0%)	0/215 (0.0%)
Investigator decision	0/1090 (0.0%)	0/398 (0.0%)	0/234 (0.0%)	0/243 (0.0%)	0/215 (0.0%)
CM intervention is no longer enrolling	1/1090 (0.1%)	1/398 (0.3%)	0/234 (0.0%)	0/243 (0.0%)	0/215 (0.0%)
Did not return for S2 within 30 days	0/1090 (0.0%)	0/398 (0.0%)	0/234 (0.0%)	0/243 (0.0%)	0/215 (0.0%)
Other	12/1090 (1.1%)	9/398 (2.3%)	0/234 (0.0%)	2/243 (0.8%)	1/215 (0.5%)

Note: This table reflects CRF Pt020 Version 3.0, 08-AUG-17; Transgender is no longer applicable from this version and only include participants who filled in the earlier version CRF.

<sup>1</sup>Screening visit 2; if a participant is rescreened and assigned a new PTID, then the corresponding old PTID is not included here.

<sup>2</sup>Reasons Not Enrolled are not mutually exclusive.

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**Listing C - Listing of 'Other' Reasons by Site**

Site	Date	Reason Given
Alabama CRS	27/02/2017	HIV viral load not completed due to lab error and participant didn't return for re-draw.
	23/05/2017	viral load not completed, only CD4 count was completed by lab.
	03/10/2017	No viral load completed
	30/11/2017	HIV status unknown (blood was destroyed at 1st screening visit)
	30/11/2017	Did not return for 2nd screening, viral load unknown
	14/12/2017	did not return for 2nd screening visit
	22/02/2017	Viral load not completed due to lab error and participant did not return.
	20/07/2017	due to lab equipment error, viral load could not be completed. We are attempting to contact parti+++
	20/07/2017	due to a lab equipment error, viral load could not be completed. We are attempting to contact participant to see if he will return for a re-draw.
JHU CRS	05/07/2016	Participant withdrew from study prior to S2 visit
	22/09/2016	participant did not want to enroll
Ponce de Leon CRS	09/01/2017	Participant moved to Ohio
	04/03/2017	No return call from participant, call multiple times